

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AFFYMETRIX, INC., a Delaware corporation,

Plaintiff/Counter-Defendant,

v.

ILLUMINA, INC., a Delaware corporation,

Defendant/Counter-Plaintiff.

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Civil Action No.: 04-901 JJF

PUBLIC VERSION

**ILLUMINA'S RESPONSE TO AFFYMETRIX'S STATEMENT OF DISPUTED FACTS IN
RESPONSE TO ILLUMINA'S MOTION FOR SUMMARY JUDGMENT OF INEQUITABLE
CONDUCT AND UNENFORCEABILITY OF U.S. PATENT NO. 6,646,243**

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INTRODUCTION

Affymetrix's response argues disputed issues of *irrelevant* fact, but does not contest the following material facts that dictate summary judgment of inequitable conduct for the '243 patent:

- Affymetrix does not contest the case law holding that patents that share a specification are "related" and thus material;
- Affymetrix does not contest that the '934 and '243 patents share the exact same specification;
- Affymetrix does not contest the case law holding that the existence of litigation involving related patents is material *per se* to a pending patent application;
- Affymetrix does not contest that at least two of the '243 patent inventors and prosecuting attorney knew of the litigation involving the related '934 patent;
- Affymetrix does not contest that the *Incyte* litigation 4507 docket number was never disclosed to the PTO;
- Regardless of the docket numbers on its various cases, Affymetrix does not contest that it never disclosed that the direct ancestor '934 patent was involved in litigation;
- Affymetrix does not contest that *all* litigation materials from *all* litigations (whether or not the docket number was disclosed) were withheld from the PTO;
- Affymetrix does not contest the case law holding that litigation materials from related litigations are material and must be disclosed;
- Affymetrix provides no explanation for why it never told the PTO about litigation involving the direct ancestor '934 patent when it did disclose the existence of litigation involving other less related patents;
- Affymetrix does not contest that the Pirrung declaration has been cited on numerous occasions to support an attack on the enablement of the '243 patent;
- Affymetrix does not contest that the '243 patent inventors and prosecuting attorney all knew of the Pirrung declaration;
- Affymetrix does not contest that the Pirrung declaration was withheld from the PTO;

- Affymetrix provides no explanation as to how the Pirrung declaration could have been withheld without an intent to deceive the PTO given that it was the subject of multiple litigations and interference proceedings.

In the face of this compelling list of undisputed facts, all Affymetrix can muster is an argument that the withheld documents were "effectively disclosed" and could have been found by the PTO Examiner if he searched hard and long enough. But the case law has never sanctioned an "effective disclosure" doctrine and it makes no sense that one could discharge its duty of disclosing material information simply because some of the information might be available publicly somewhere – all prior art is public to some extent, but that does not mean that there is no duty to specifically disclose it to the PTO. It is hard to imagine more material information to withhold from the PTO than (1) litigation involving invalidity and unenforceability attacks on a direct ancestor patent that shares the exact same specification as the pending application, and (2) a declaration from the lead inventor on the pending application stating that the technology was not enabled on the date to which the pending application purports to claim priority. Affymetrix's arguments cannot create a *genuine* dispute of material fact, and thus do not preclude a finding of summary judgment of inequitable conduct.

ARGUMENT

I. AFFYMETRIX HAS NOT RAISED A GENUINE DISPUTE OF MATERIAL FACT WITH RESPECT TO ITS FAILURE TO DISCLOSE THE 4507 LITIGATION WITH INTENT TO DECEIVE THE PTO

A. The Subject Matter of the '243 Patent Was Involved in the 4507 Litigation

1. Affymetrix incorrectly states the law regarding a patent applicant's duty to disclose prior litigations. Despite the fact that both patents share the exact same specification, Affymetrix contends that, because the '934 is a divisional patent with different claims, it somehow follows that the '934 patent does not concern the subject matter of the '243 patent. (Affymetrix St. ¶ 10) Affymetrix does not cite any legal authority to justify this theory. In fact,

Affymetrix's theory is directly contrary to established case law. *Nilssen v. Osram Sylvania, Inc.*, No. 01 C 3585, 2006 WL 1891807 at *21 (N.D. Ill. July 5, 2006) ("Ongoing litigation is material if the patent involved in the litigation shares the same specification and discloses the same subject matter as the pending patent."); *DaimlerChrysler AG v. Feuling Adv. Tech., Inc.*, 276 F. Supp.2d 1054, 1063 n.4 (S.D. Cal. 2003) (patents that were continuations-in-part necessarily involved the same subject matter as an ancestor patent); *ICU Medical, Inc. v. B. Braun Medical, Inc.*, No. C 01-3202, 2005 WL 588341 at *15 (N.D. Cal. March 14, 2005) ("Indeed, even ICU does not dispute that this ongoing litigation [involving the '204 patent] was material to the '673 patent prosecution...The '204 patent shared the same specification and disclosed the same subject matter as the '673 application."); *Nisus Corp. v. Perma-Chink Systems, Inc.*, 421 F.Supp. 2d 1084, 1104 (E.D. Tenn. 2006) (finding that litigation involving an ancestor patent was a related litigation involving the same subject matter as the child patent application). Therefore, according to established case law, the 4507 litigation involving the '934 patent involved the same subject matter as the '243 patent because it shared the same specification and disclosed the same subject matter. *Id.*

2. Affymetrix also erroneously states the law regarding materiality when it contends that litigation involving the subject matter of a patent application being prosecuted is not material *per se*. (Affymetrix St. ¶¶ 6, 9, 34, 48-49) This is, again, directly contrary to established case law. *Nilssen*, 2006 WL 1891807 *21 (N.D. Ill. 2006) ("Related litigation' is *per se* material information covered by the duty of disclosure."); *DaimlerChrysler AG*, 276 F.Supp.2d at 1063 ("Section 2001 refers to 'the existence of the litigation *and any other material* information.' (emphasis added). Thus, under the MPEP, litigation is material *per se*"); *Nisus Corp.*, 421 F.Supp.2d at 1104 ("[R]elated litigation is *per se* material information covered by the

duty of disclosure."); *ICU Medical*, 2005 WL 588341 at *14 ("In fact, related litigation is material *per se*"). In accordance with the case law, the existence of the 4507 litigation, which involved the subject matter of the '243 patent, is material *per se*. *Id.*

B. The 4507 Litigation, and the Fact that the '934 Ancestor Patent Was In Litigation, Was Not Disclosed to the PTO

3. Affymetrix provides an extensive, and largely irrelevant, description of all of their litigations in the 1998-2001 timeframe. (Affymetrix St. ¶¶ 13-26) The discussion of docket numbers and "effective disclosure" is irrelevant in light of the key facts and law.

4. Affymetrix does not and cannot dispute that it never disclosed the litigation under the 4507 docket number to the PTO.

5. Affymetrix did disclose litigations that involved patents that were not direct ancestors of the '243 patent. The disclosed litigations had different docket numbers, and Affymetrix did not disclose the dockets or other litigation documents from those cases.

6. While Affymetrix would like to turn this all into an issue of confusion over docket numbers, the point is that Affymetrix did not disclose that the '934 patent – the only direct ancestor to the '243 patent that was involved in the *Incyte* cases – was involved in litigation. This failure to disclose even the existence of litigation involving the '934 patent – magnified by the disclosure of other, less relevant litigations and patents – proves that this was more than just confusion over docket numbers.

7. Affymetrix failed to disclose the involvement of the '934 patent in litigation in four consecutive prosecutions involving the '243 patent and the applications leading up to its issuance.¹

C. Affymetrix Does Not Create a Genuine Dispute of Material Fact With Its Argument That The Disclosure of the 4508 Litigation "Effectively Discloses" The Inequitable Conduct Allegations and Incyte's Initial Disclosure of Prior Art from the 4507 Litigation

8. Affymetrix's theory that merely disclosing the existence of the 4508 litigation "effectively disclosed" the inequitable conduct allegations and initial disclosure of prior art from the 4507 litigation has no sound legal basis and does not create a genuine issue of material fact with respect to Illumina's allegations of inequitable conduct regarding the '243 patent. (Affymetrix St. ¶¶ 34-36)

9. First, it is the applicant's *affirmative duty* to bring all material information to the attention of the Examiner and not the Examiner's job to blindly search litigation dockets for documents that might be material. *Evident Corp. v. Church & Dwight, Co., Inc.*, 399 F.3d 1310, 1315-16 (Fed. Cir. 2005) ("Under the regulations, inventors, patent owners, and attorneys associated with the filing or prosecution of a patent application have an affirmative and continuing duty to disclose material information to the PTO.").

10. Courts have specifically rejected an "effective disclosure" doctrine that would allow patent applicants to discharge their duty of disclosure if the examiner could have found the material prior art if it searched for it in public databases. *See Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc.*, 326 F.3d 1226, 1241 (Fed. Cir. 2003) (holding that applicant's

¹ Affymetrix failed to disclose the 4507 litigation by docket number or the involvement of the '934 patent in litigation during the prosecution of U.S. Pat. App. Nos. 08/456,598, 09/129,470, 09/690,191, and 10/098,203.

duty of disclosure to the PTO is not satisfied by the fact that a material reference was published and thus publicly available).

11. Second, Affymetrix did not even provide to the PTO a copy of the 4508 and 03192 litigation dockets for the Examiner to review to perform the cross-referencing analysis that Affymetrix posits.

12. Third, even if Affymetrix's "effective disclosure" doctrine found some basis in the law (which it does not), the examiner still could not have obtained many of the pleadings from the 4507 litigation because they were filed under seal. (*See* Illumina Br. Ex. F - 4507 docket; *See* Illumina Br. Ex. H - 99-cv-21164 docket)² And whether certain pleadings from the 4507 litigation were similar to pleadings in the other litigations or not, the pleadings in the other litigations were similarly filed under seal and inaccessible to the examiner.

13. Affymetrix states that Incyte's disclosures of prior art and the inequitable conduct allegations from the 4508 litigation are "nearly identical" to those from the 4507 litigation. (Affymetrix St. ¶¶ 34-36) Even if true, this is immaterial. Because Affymetrix never provided the Examiner with *any* documents from the 4507 or 4508 litigations, the Examiner was never informed of the specific inequitable conduct allegations or Incyte's disclosures of prior art from either litigation. The inequitable conduct allegations from the 4507 litigation cannot be cumulative of information not of record before the Examiner.

14. Affymetrix also asserts that it offered in the May 30, 2002 IDS to provide the examiner with documents from the disclosed litigations, which did not include the 4507 litigation, if only the Examiner had requested such documents. (Affymetrix St. ¶¶ 27, 28, 36;

² The consolidated 4507 litigation was reassigned on December 6, 1999 and proceeded as 99-cv-21164. (*See* Ex. H).

See Illumina Br. Ex. I - Information Disclosure Statement dated 5/30/2002) However, this does not fulfill Affymetrix's duty of candor and good faith. "Under the regulations, inventors, patent owners, and attorneys associated with the filing or prosecution of a patent application have an *affirmative and continuing duty to disclose* material information to the PTO." *Evident Corp.*, 399 F.3d at 1315-16 (emphasis added). An offer to disclose, especially without providing the Examiner any detail as to what was contained in the pleadings or documents, does not meet the duty to disclose.

D. Affymetrix Cannot Explain Its Withholding of Material Litigation Documents By Pointing to its Disclosure of Prior Art.

15. Affymetrix provides a lengthy description of their disclosure of prior art from the 4507 and 4508 litigations. (Affymetrix St. ¶¶ 29-33) This entire section is irrelevant as it does not pertain to either of the two grounds of inequitable conduct that are at issue in this motion.³

E. Affymetrix Does Not Dispute Evidence That The Inventors Acted With An Intent to Deceive The PTO By Not Disclosing The 4507 Litigation

16. The 4507 litigation, which involved allegations of invalidity and unenforceability of a patent that shares the same specification as the '243 patent, was material *per se* to the patentability of the '243 patent.

17. In its opening memorandum, Illumina explained the evidence that two of the inventors of the '243 patent, Dr. Fodor and Dr. Stryer, were aware of the litigation and did

³ In any event, Affymetrix does not dispute that it withheld references identified by Incyte and Synteni in the 4507 litigation. (Affymetrix St. ¶ 32) Furthermore, while Affymetrix may have disclosed prior art, it did not disclose Incyte's Initial Disclosures of Prior Art which would have informed the Examiner which art or specific combinations of art render the claims anticipated or invalid, respectively. To be clear, Affymetrix did not discharge its duty of disclosure for *any* of the litigations since it provided none of the material documents from these litigations; it is just that its conduct with respect to withholding the 4507 litigation and the fact that a direct ancestor patent was involved is an even more egregious act of inequitable conduct.

not disclose it to the PTO during the prosecution of the '243 patent. (*See* Illumina Br. Ex. C - Affymetrix's 1998 10-K SEC filing; *See* Illumina Br. Ex. D - Affymetrix's 2000 10-K SEC filing.) Affymetrix did not even attempt to dispute this evidence. Nor does Affymetrix offer any explanation as to how Dr. Fodor and Dr. Stryer were motivated by anything but an intent to deceive the PTO in failing to disclose the litigation materials. This failure to respond equates to an admission to the inventor's intent to deceive.

18. Beyond the uncontested intent of the inventors, the conclusory denial contained in Mr. McGarrigle's declaration regarding his intent in withholding the litigation materials is not enough to rebut the strong inference of intent against him. (McGarrigle decl. ¶¶ 28); *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1275 (Fed. Cir. 2001) ("A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice."). Moreover, as discussed below, the Court should strike the declaration of Mr. McGarrigle as Affymetrix has failed to produce him for deposition in this matter.

II. AFFYMETRIX HAS NOT RAISED A GENUINE DISPUTE OF MATERIAL FACT WITH RESPECT TO ITS FAILURE TO DISCLOSE THE PIRRUNG DECLARATION WITH INTENT TO DECEIVE THE PTO

A. The Pirrung Declaration Was Not Disclosed to the PTO

19. It is undisputed that Affymetrix did not disclose or provide the Pirrung declaration to the PTO.

20. Affymetrix, however, argues that it provided the Examiner with places where, if the Examiner had gone and looked hard enough, the Pirrung declaration could have been obtained. (Affymetrix St. ¶¶ 37-41) Although Affymetrix did not provide any documents from these proceedings, Affymetrix asserts that the Pirrung declaration was available from the

dockets of the 4508 litigation and the European Patent Office's opposition proceedings for EP 619,321.⁴ (Affymetrix St. ¶¶ 37-41) Affymetrix admits that only the redacted versions of the Pirrung declaration were available in those locations, so the declaration was not fully available in any event.

21. Moreover, Affymetrix has an affirmative duty to provide material information to the PTO regardless of whether such information was available by other means to the Examiner. *Evident Corp.*, 399 F.3d at 1315-16. Even though all prior art is at some level publicly available, an applicant must still disclose material prior art to the PTO. *Bristol-Myers Squibb Co.*, 326 F.3d at 1241. Therefore, it is irrelevant whether or not the Examiner could have found the Pirrung declaration – it was Affymetrix's affirmative duty to provide the Pirrung declaration to the Examiner. *Evident Corp.*, 399 F.3d at 1315-16.

B. The Pirrung Declaration Was Material To Prosecution

22. Affymetrix's argument that the PTO had considered and rejected the "substance of the Pirrung arguments" is unsupported by any evidence cited in Affymetrix's Statement. (Affymetrix St. ¶¶ 43-45) Affymetrix provides no evidence that the PTO ever considered the Pirrung declaration, let alone rejected the evidence of non-enablement offered by Dr. Pirrung. In fact, the exhibits cited by Affymetrix in support of their argument do not ever reference the Pirrung declaration. (See Affymetrix St. Ex. 10 - Decision from Interference No. 104,358; See Affymetrix St. Ex. 11-Decision from Interference No. 104,359)

⁴ Affymetrix has not provided any evidence that the Pirrung declaration was submitted in connection with the 104,358 and 104,359 interferences. The exhibits that Affymetrix cites to for this point do not mention the Pirrung declaration and merely refer to a declaration by Dr. Kricka in which he discusses two Pirrung articles from the 1990's. (See Affymetrix St. Ex. 10; See Affymetrix St. Ex. 11) Of course, Affymetrix did not provide the Kricka declaration to the PTO in the course of the '243 patent prosecution either.

23. Affymetrix misleadingly states that "Pirrung's work" was found to support a finding of enablement in the interference proceedings. (Affymetrix St. ¶¶ 6, 44-45) However, "Pirrung's work" that is referred to by Affymetrix is an article written by Dr. Pirrung in 1995 – five years after the time period discussed in the Pirrung declaration and five years after the time period that is relevant to the enablement of the '243 patent – and not to the Pirrung declaration at issue. (Affymetrix St. ¶¶ 6, 44-45) Therefore, Affymetrix's discussion of "Pirrung's work" is irrelevant to Illumina's inequitable conduct allegations.

24. Affymetrix's suggestion that the 1995 article by Dr. Pirrung supported the enablement of the claims of the '243 patent is misleading. During these same interference proceedings, Affymetrix argued that its VLSIPS light-directed synthesis method on a flat substrate was enabled by distinguishing the 1995 article authored by Dr. Pirrung in which he describes the fundamental problems associated with synthesizing nucleic acids *on beads* using VLSIPS. (See Illumina Resp. Ex. Z - Declaration of Dennis W. Solas at ¶ 13). Because the claims of the '243 patent concern substrates comprising beads as opposed to flat surfaces, the arguments that Affymetrix made during the interference proceedings support the non-enablement of the claims of the '243 patent. (Again, these arguments were not disclosed to the examiner either.)

25. Furthermore, Affymetrix's argument is premised on an incorrect statement of the law. Whether a document actually proves invalidity is a completely separate issue from whether it is material in the context of inequitable conduct. *Bristol-Myers Squibb*, 326 F.3d at 1238-39 (Fed. Cir. 2003) ("[W]hether a reference would be considered important by a reasonable examiner in determining whether a patent application is allowable, including whether the invention is enabled, is a separate issue from whether the invention is actually enabled."); *Li*

Second Family Ltd. Partnership v. Toshiba Corp., 231 F.3d 1373, 1380-81 (Fed. Cir. 2000) ("[T]he test for materiality is whether a reasonable examiner would have considered the information important, not whether the information would conclusively decide the issue of patentability.").

26. Contrary to Affymetrix's assertion that the Pirrung declaration only mentions the '992 patent, the Pirrung declaration explains why the VLSIPS synthesis method discussed in the '854 patent, a parent of the '243 and '934 patents which shares the same specification, was not enabled as of 1990. (See Illumina Br. Ex. N - Pirrung decl. ¶ 26-27; Affymetrix St. ¶¶ 43, 46-47) Therefore, the Pirrung declaration is material as it discusses the non-enablement of the VLSIPS method of nucleic acid synthesis that is described to make the arrays claimed in the '243 patent.

C. Affymetrix Does Not Dispute Evidence That The Inventors Acted With Intent to Deceive The PTO By Not Disclosing the Pirrung Declaration

27. The Pirrung declaration is highly material under the reasonable examiner standard and under 37 C.F.R. 1.56(b).⁵

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Moreover, prior to the filing of the '243 patent, it is undisputed that *each* of the three other inventors of the '243 patent – Dr. Stryer, Dr. Read and Dr. Fodor – were familiar with the contents of the Pirrung declaration. Affymetrix

⁵ The Pirrung declaration is also material under 37 C.F.R. § 1.56(b)(ii) as a statement that refutes, or is inconsistent with, a position that Affymetrix took in asserting an argument of patentability. In prosecuting the '243 patent, Affymetrix took the position that the VLSIPS method to manufacture high density nucleic acid arrays was enabled, and claimed priority to March 7, 1990 to contend that certain cited art was not prior art. However, the Pirrung declaration, which states that the VLSIPS method could not be used in this manner in the 1990 time frame, is inconsistent with Affymetrix's position that VLSIPS was enabled as of March 7, 1990.

does not dispute the fact that these inventors acted with intent to deceive the PTO when they failed to disclose the Pirrung declaration during the prosecution of the '243 patent. Therefore, there is no issue of material fact with respect to the inventors' intent to deceive the PTO.

28. Beyond the uncontested intent of the inventors, the conclusory denial contained in Mr. McGarrigle's declaration regarding his intent in withholding the Pirrung declaration is not enough to rebut the strong inference of intent against him. (McGarrigle decl. ¶¶ 24, 28); *GFI, Inc.*, 265 F.3d at 1275 (Fed. Cir. 2001) ("A mere denial of intent to mislead (which would defeat every effort to establish inequitable conduct) will not suffice.").

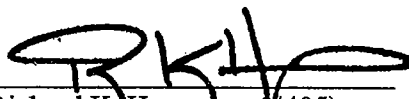
D. The Court Should Strike the Declaration of Phillip L. McGarrigle

29. Illumina noticed the deposition of Mr. McGarrigle on December 21, 2005. (D.I. 135) As was the case with certain other fact depositions, the parties were unable to arrange a date for this deposition prior to the close of fact discovery. Although these other depositions have been completed, Illumina has over the past 5 months repeatedly requested Affymetrix to advise of Mr. McGarrigle's availability for deposition. Affymetrix has refused to provide Mr. McGarrigle for deposition on the basis that his schedule was too busy. (*See* Illumina Resp. Ex. AA - Letter from Collier to Gross dated 5/25/06; *See* Illumina Resp. Ex. BB - Letter from Gross to Collier dated 5/26/06) It is ironic that Mr. McGarrigle had the time to prepare a declaration but has no time for a deposition. Affymetrix's attempt to rely on the testimony of a witness that they have refused to make available for deposition is highly prejudicial to Illumina. Therefore, Illumina requests that the Court strike the declaration of Phillip L. McGarrigle.

CONCLUSION

For the foregoing reasons and those set forth in its opening briefing, Illumina respectfully requests that the Court enter summary judgment of unenforceability of the '243 patent due to Affymetrix's inequitable conduct during the prosecution of the '243 patent.

Dated: August 4, 2006



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CERTIFICATE OF SERVICE

I hereby certify that on this 16th day of August, 2006, I caused to be electronically filed the foregoing document, **REDACTED VERSION OF ILLUMINA'S RESPONSE TO AFFYMETRIX'S STATEMENT OF DISPUTED FACTS IN RESPONSE TO ILLUMINA'S MOTION FOR SUMMARY JUDGMENT OF INEQUITABLE CONDUCT AND UNENFORCEABILITY OF U.S. PATENT NO. 6,646,243**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

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